

Amendments to the Claims:

This listing of claims will replace all prior versions and listings of claims in the application:

Listing of Claims:

1. (Currently Amended) A lateral flow method for the determination of an analyte in a sample involving utilizing biospecific affinity reactions, and comprising the following steps:

i. forming a complex in a lateral flow matrix, the complex comprising:

Reactant I---Analyte'---Reactant*, where

a. Reactant* and Reactant I exhibit biospecific affinity to the analyte,

b. Reactant* is analytically detectable,

c. Analyte' is the analyte or an analyte-related reactant, and subsequently

ii. determining a detectable signal constituting a sample value from Reactant* in the complex ~~(sample value)~~, and

iii. ~~obtaining~~ determining the amount of analyte in the sample by comparing the sample value with one or more calibrator values, each of which corresponds to a standard amount of analyte,

wherein A) before determination of the calibrator value, either (i) calibrator, or (ii) a binder for the calibrator has been bound to a matrix, and when a binder for the calibrator has been bound to the matrix, calibrator is added or calibrator predeposited in the matrix is released for binding with the binder, and at the determination of calibrator value, and wherein the matrix is insoluble in the liquid medium in which binding of Reactant* to the calibrator occurs, B) the calibrator and the analyte exhibit biospecific affinity ~~are capable of~~ biospecifically binding to Reactant* by equivalent binding sites, and C) one or more

calibrator zones CZ comprising calibrator or binder for the calibrator are located in a single process flow stream with Reactant I in a detection zone (DZ).

2. (Previously Presented) The method according to claim 1, wherein calibrator has been bound to the matrix before the determination of calibrator value.

3. (Previously Presented) The method according to claim 1, wherein a binder for the calibrator has been bound to the matrix before the determination of calibrator value.

4. (Previously Presented) The method according to claim 1, wherein the binder for the calibrator is one member of a specific binding pair, and the other member of the specific binding pair is coupled or conjugated to the calibrator.

5. (Cancelled).

6. (Previously Presented) The method according to claim 1, wherein

a. (i) each calibrator zone comprises calibrator in an amount corresponding to a standard amount of analyte, or

(ii) each calibrator zone contains calibrator binder, the amount of calibrator binder and the amount of calibrator corresponding to a standard amount of analyte, and

b. Reactant* is bound to the calibrator by transporting Reactant* through the calibrator zones.

7-10. (Cancelled).

11. (Previously Presented) The method according to claim 1, wherein along a single matrix is the flow matrix, and wherein along a single process flow stream, there are

a. one or more calibrator zones (CZ), each of which exhibits a matrix calibrator or a matrix calibrator binder,

b. one or more detection zones (DZ), none of which coincides with any calibrator zone, and in which a Capturer is firmly anchored and is either Reactant I or a biospecific affinity reactant, which directly or indirectly binds Reactant I biospecifically,

c. an application zone for Reactant*, $A_R \cdot Z$, which is located upstream of said CZ and DZ and to which Reactant* is optionally predeposited, and

d. an application zone for sample ($A_S Z$) which is located

i. upstream of or coinciding with a detection zone,

ii. downstream or upstream of or coinciding with $A_R \cdot Z$ ($A_S Z / A_R \cdot Z$), or

iii. upstream of, downstream of or coinciding with a calibrator zone,

wherein Reactant* is added to $A_R \cdot Z$ if Reactant* is not predeposited, or buffer is added to $A_R \cdot Z$ if Reactant* is predeposited, and sample is added to $A_S Z$, optionally premixed with Reactant* if $A_S Z$ and $A_R \cdot Z$ coincide, such that analyte and Reactant* reach DZ at the same time, or such that analyte reaches DZ before Reactant*.

12. (Currently Amended) The method according to claim 11, wherein the calibrator zone or zones CZ comprise ~~exhibit~~ a calibrator binder, and calibrator is predeposited upstream of the calibrator zone or zones.

13. (Previously Presented) The method according to claim 11, wherein the process flow stream comprises two or more of said calibrator zones.

14. (Currently Amended) The method according to claim 11, wherein the process flow stream comprises one or two of said calibrator zones, and the level of analyte in the sample is obtained by:

a. ~~having access to one or more separately obtained calibrator values, and~~
b. comparing a calibrator value from one of the ~~for a calibrator zones zone~~
(~~Positive Internal Calibrator = PIC~~), located in the process flow stream including the detection zone, with one or more ~~of the~~ separately obtained calibrator values to determine a deviation between the measured calibrator value and the separately obtained calibrator values,
and,

b e. adjusting ~~adapting~~ the sample value measurement signal from the detection zone ~~by to the deviation of the measurement signal for PIC from the separate calibrator values,~~ and subsequently obtaining the level of analyte in the sample by comparing the adjusted sample value ~~adapted measurement signal from the detection zone~~ with one or more of the separately obtained calibrator values.

15. (Currently Amended) The method according to claim 11, wherein
a. $A_S Z$ is (i) common to $A_R \cdot Z$, forming a common zone ($= A_S Z / A_R \cdot Z$) or (ii) is located upstream of $A_R \cdot Z$, and

b. for alternative (i) sample is premixed with Reactant* before it is added to the common zone $A_S Z / A_R \cdot Z$, or sample is added to the common zone $A_S Z / A_R \cdot Z$ containing predeposited Reactant*, or for alternative (ii), sample is added to $A_S Z$, which is located upstream of $A_R \cdot Z$ which in turn comprises predeposited Reactant*.

16. (Previously Presented) The method according to claim 6, wherein Reactant* has particles as an analytically detectable group, and/or calibrator or calibrator binder is/are anchored to the matrix by particles.

17. (Previously Presented) The method according to claim 1, wherein the analyte is an antibody directed to Reactant I or to Reactant*, and

a. Reactant* is an antibody directed to the analyte and Reactant I is an antigen or hapten, when the analyte is an antibody directed to Reactant I, or

b. Reactant* is an antigen or a hapten and Reactant I is an antibody directed to the analyte, when the analyte is an antibody directed to Reactant*.

18. (Previously Presented) The method according to claim 1, wherein the analyte is an antigen, and Reactant* and Reactant I are antibodies directed to the analyte.

19. (Previously Presented) The method according to claim 1, wherein the method is performed as a part of diagnosing allergy or autoimmune disease.

20. (Currently Amended) A device for transforming measured signal values of a complexed, analytically detectable reactant (=Reactant*) to real amounts of analyte in a sample, in connection with performing an analysis method which utilizes biospecific affinity reactions for the determination of the amount of analyte in a sample, to form complexes comprising Reactant* in an amount which is related to the amount of analyte in the sample, wherein the device comprises ~~exhibits~~:

a flow matrix in which there is an area of process flow for the transport of Reactant*, and wherein there are in said area

- i. one or more calibrator zones (CZ) comprising a calibrator, or binder for the calibrator, which is firmly anchored to the matrix, the amounts of calibrator or calibrator binder, respectively, being different for at least two calibrator zones when at least two calibrator zones are present, and the calibrator exhibiting binding sites to which Reactant* binds, when Reactant* is transported through a calibrator zone,
- ii. an application zone for Reactant* ($A_R \cdot Z$) upstream of said calibrator zones, and
- iii. one or more detection zones (DZ), all of the detection zones being downstream of all of the said calibrator zones.

21. (Previously Presented) The device according to claim 20, wherein a calibrator binder is firmly anchored in the matrix and the device comprises calibrator predeposited upstream of the calibrator zone.

22. (Previously Presented) The device according to claim 20, wherein the device comprises Reactant* predeposited in $A_R \cdot Z$.

23. (Currently Amended) The device according to claim 20, wherein the process flow comprises a detection zone (DZ) which is located downstream of $A_R \cdot Z$ and comprises a firmly anchored Capturer to via which Reactant* can bind in the ~~to~~ DZ, and a zone of application of sample ($A_S Z$) which is located upstream of or coincides with said DZ.

24. (Previously Presented) The device according to claim 23, wherein $A_R \cdot Z$ is located upstream of or downstream of or coincides with $A_S Z$.

25. (Previously Presented) The device according to claim 23, wherein the firmly anchored reactant (Capturer) has biospecific affinity to the analyte or to an analyte-related reactant.

26. (Previously Presented) The device according to claim 23, wherein the firmly anchored reactant (Capturer) has biospecific affinity to a second reactant which in turn has biospecific affinity to the analyte or to an analyte-related reactant.

27. (Previously Presented) The device according to claim 23, wherein said one or more calibrator zones are located upstream of DZ.

28. (Previously Presented) The device according to claim 23, wherein A₅Z is located upstream of all calibrator zones.

29. (Previously Presented) A test kit, comprising a device according to claim 20.

30. (Previously Presented) The kit according to claim 29, wherein the kit comprises Reactant*.

31. (Previously Presented) The kit according to claim 29, wherein the kit comprises calibrator when said device has the calibrator binder bound to the matrix.

32. (Previously Presented) The device according to claim 20, wherein Reactant* has biospecific affinity to analyte or an analyte-related reactant and to the calibrator.

33. (New) The method according to claim 1, wherein all of the detection zones DZ are downstream of all of the calibrator zones CZ in the lateral flow matrix.

34. (New) The method according to claim 1, wherein Reactant* comprises a fluorophore group or a chromogenic group.

35. (New) The method according to claim 1, wherein Reactant* comprises metal particles or nonmetal particles.

36. (New) The method according to claim 1, wherein Reactant* comprises gold sol particles.

37. (New) The device according to claim 20, wherein Reactant* comprises a fluorophore group or a chromogenic group.

38. (New) The device according to claim 20, wherein Reactant* comprises metal particles or nonmetal particles.

39. (New) The device according to claim 20, wherein Reactant* comprises gold sol particles.